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1 P R O C E E D I N G S

2 (10:05 a.m.)

3 CHIEF JUSTICE ROBERTS: We'll hear argument
4 first this morning in Case 10-844, Caraco Pharmaceutical
5 Laboratories v. Novo Nordisk.

6 Mr. Hurst.

7 ORAL ARGUMENT OF JAMES F. HURST

8 ON BEHALF OF THE PETITIONERS

9 MR. HURST: Mr. Chief Justice, and may it
10 please the Court:

11 Since 1984, whenever an -- a drug has
12 multiple FDA-approved uses, there has been a statutory
13 path for generic drugs to reach the market if there are
14 specific uses not covered by a patent. Here, there is
15 no dispute that Novo's patent does not claim the use of
16 repaglinide when used alone, and that is "an approved
17 method" of using the drug. Even though that matches the
18 statutory language exactly, Novo is arguing that in this
19 case, our counterclaim to correct their blocking use
20 code is thwarted by the fact that their patent does
21 claim a different approved use --

22 JUSTICE GINSBURG: Is it first -- is it
23 first approved, the drug itself -- they're not
24 claiming that, because that -- that patent has expired,
25 hasn't it?

1 MR. HURST: That patent has long expired,
2 and they also had a patent using -- for the use of the
3 drug to treat diabetes through any method, and that
4 patent has long expired. The only patent that's left
5 that Novo has is specifically limited to the use of
6 repaglinide in combination with metformin to treat
7 diabetes. My client, Caraco, is attempting to get on
8 the market for admittedly non-infringing uses, which
9 occupy about 70 percent of the marketplace out there.

10 JUSTICE ALITO: Suppose I said your brief
11 does not cite a Supreme Court decision. Would that be a
12 correct statement?

13 MR. HURST: I believe that -- that -- if --
14 it depends on the context of the sentence, but I think
15 that would be a correct statement if I understand the
16 way you are asking the question.

17 You are asking the question in a way that
18 suggests to me by context, you're asking whether I cite
19 any Supreme Court precedent. But the context here is a
20 little bit different, because the context here in the
21 counterclaim is a situation where drugs routinely have
22 multiple and different distinct uses. And in that
23 context --

24 JUSTICE ALITO: Well, we have hundreds and
25 hundreds, probably thousands of opinions, and you didn't

1 cite -- there were many of them that you didn't cite.
2 You cited quite a few, but you didn't cite all of them.

3 MR. HURST: That's true, that's true. But
4 when a judge -- when a judge says to me that, you know,
5 you are going to lose this case because you didn't cite
6 an applicable precedent, I am going to hear that to mean
7 I didn't cite a specific particular case. There are
8 many ways to use the word "an" after the word "not"
9 where it clearly does not mean "any." For instance:
10 "The prosecutor failed to get a conviction because she
11 did not prove an element of the offense." "I got lost
12 on my way to the party because I failed to make a turn."
13 "My cake fell because I did not include an ingredient."
14 So the context speaks volumes in terms of whether or not
15 "an" means "any" in any particular context.

16 JUSTICE SCALIA: But -- but the context
17 here, one would expect it to say, if it meant what you
18 say it meant, a -- did not claim a use asserted by the
19 generic.

20 MR. HURST: Justice Scalia -- you're --

21 JUSTICE SCALIA: But not just "did not claim
22 a use" and we have to fill in, that is "the use asserted
23 by the generic." That's a strange thing to fill in.

24 MR. HURST: Justice Scalia, I am not
25 quibbling with the fact that this could -- the statute

1 could have been written more elegantly. My guess is
2 that almost every statute this Court is asked to
3 construe, there are different ways that it could have
4 been written to resolve the issue in question.

5 JUSTICE SCALIA: It's not a matter of
6 elegance. It's a matter of how I would have expected it
7 to be -- to be framed if it meant what you -- what you
8 say it means. It's -- so easy to say that, does not
9 claim the use asserted by the generic. My goodness --
10 and that's what you say it means.

11 MR. HURST: If -- and look at the context.
12 The statute does not ask the brand company to identify
13 an approved use that the patent does claim. It puts the
14 burden on the ANDA applicant to come into court, file a
15 counterclaim, and identify an approved use that the
16 patent does not claim. We've carried that burden twice
17 over. There are two approved uses that the patent does
18 not claim. Context --

19 JUSTICE ALITO: As I understand your
20 argument, you satisfy the -- the ground for seeking
21 deletion or correction was satisfied even before Novo
22 wrote the new use code that you claim is overly broad.
23 When the use code said simply the use of repaglinide
24 with metformin, the -- the ground for seeking deletion
25 or correction was satisfied, wasn't it?

1 MR. HURST: Well, I mean -- the truth is the
2 patent -- yes -- the answer to that question is yes.
3 But I would have no reason to go into court to fix a use
4 code that is not blocking me.

5 JUSTICE ALITO: No, but that's another -- so
6 there are two oddities in the way you read the statute.
7 Now, maybe Congress just did a bad job of drafting. But
8 the first is the one we were discussing before, and
9 that's the second one, that -- your -- your beef really
10 is not that the patent does not include every use. Your
11 beef is that the source -- the use code is too broad,
12 and yet that is not the ground that the statute sets out
13 for seeking deletion or correction.

14 MR. HURST: I believe it does, because it
15 talks about -- there's two remedies: the deletion
16 remedy and the correction remedy. As we read the
17 statute, we preserve distinct roles for the correction
18 remedy and the deletion remedy. As Novo reads this
19 statute, they all but acknowledge that they are writing
20 the word "correct" out of the statute, because there is
21 no meaningful role for the correction remedy as Novo is
22 reading this statute.

23 They call the correction remedy a -- a relic
24 of a failed bill. And in fact, they haven't identified
25 any meaningful role for the word "correct" in the

1 statute as they read this statute.

2 Remember, what they say is there is two
3 pieces of information that qualify as patent
4 information: expiration dates and patent numbers.
5 Nothing else. The correction remedy can never reach an
6 expiration date under any circumstances.

7 I haven't heard Novo to argue otherwise.
8 What they're saying is if a patent is correctly listed
9 in the Orange Book, this counterclaim is unavailable.
10 So what does that mean? If the brand company
11 incorrectly lists the expiration date for a properly
12 listed patent as 2150, this counterclaim is not
13 available to correct the expiration date.

14 So that leaves only one single piece of
15 information that could possibly be addressed by the
16 correction remedy. And what does Novo say? Patent
17 numbers: They say well, the correction remedy could be
18 available for fixing typos in a patent.

19 JUSTICE SCALIA: Well, it's not much, but
20 it's something.

21 (Laughter.)

22 JUSTICE SCALIA: And -- and the way you are
23 talking, you seem to assume that all the problems in the
24 world have to be addressed by this statute. Would you
25 have no remedy by -- by suing the FCC for accepting uses

1 that -- that it should not have accepted?

2 MR. HURST: I -- whether I do have
3 alternative remedies doesn't answer the question about
4 whether I have a remedy in -- for this particular
5 counterclaim.

6 JUSTICE SCALIA: That's true, but if -- but
7 if you have alternative remedies, I am not terribly
8 shocked by the fact that you don't have a remedy under
9 this statute.

10 MR. HURST: I don't have any good remedies
11 under this statute. I could not, Justice Scalia, sue
12 the FDA for accepting the use code, at least based on
13 existing law, because the FDA's position is that their
14 role with respect to patents is purely ministerial.
15 That has been upheld for about a decade now, including
16 multiple courts of appeals, the Federal Circuit and the
17 D.C. Circuit. So my ability to sue the FDA for
18 accepting Novo's incorrect use code is not really a true
19 alternative remedy.

20 The remedy that Congress gave me, that I --
21 that we think Congress gave us, is an enormously
22 efficient remedy. We filed our counterclaim and within
23 3-1/2 months we got an injunction asking Novo to correct
24 its use code.

25 JUSTICE ALITO: Suppose you didn't

1 file the -- suppose the counterclaim provision wasn't
2 available, and Novo -- you filed a paragraph IV
3 certification and Novo sues you for infringement. Could
4 you not defend the infringement action on the ground
5 that your use of the -- of the drug was not in -- did
6 not infringe their patent?

7 MR. HURST: I could not.

8 JUSTICE ALITO: Why -- why is that?

9 MR. HURST: Because there's two paths that
10 are available under the FDA to get -- for a generic to
11 get approval. One is section (viii), and if I proceed
12 under section (viii) I can carve out the patented use
13 from my label. If -- and Your Honor's question assumed
14 I went through the other route, paragraph IV. I am
15 not -- FDA does not allow you to carve out any portion
16 of your label if you are proceeding under paragraph IV.
17 So in the circumstance that you just described, I
18 would -- I would be infringing under paragraph IV and
19 the only way for me to get on the market is to
20 invalidate the patent.

21 Now, think about what that means. Novo is
22 forcing us, essentially, to infringe. We don't want to
23 infringe. We are trying to carve out our label so that
24 we can proceed under section (viii). They have blocked
25 our ability to use section (viii), so they've forced us

1 into paragraph IV, forced us to infringe. And what
2 happens if we fail to invalidate the patent? We are
3 kept off the market until 2018 for admittedly
4 noninfringing uses of the drug. There are two
5 admittedly noninfringing uses of the drug. That's where
6 we want -- that's what we want to use to get to the
7 market.

8 JUSTICE KAGAN: Mr. Hurst, would -- would
9 you agree that Congress did not contemplate this
10 situation? As I understand it, it wasn't until 2003
11 that the FDA allowed companies to write their own use
12 codes, and that's what creates this problem. So would
13 you agree that the Congress that passed this act really
14 couldn't have had this situation in mind?

15 MR. HURST: I wouldn't agree, because look
16 at the timing. The FDA issued the regulation entitled
17 "Submission of Patent" -- "Submission of Patent
18 Information" in June of 2003. Congress enacted this
19 counterclaim using the same language in December of
20 2003. The submission of patent information regulation
21 by the FDA with respect to method-of-use patents, and
22 that's what we are talking about here, is all about
23 ensuring that the use code itself is accurate and
24 correct and matches up with the patent.

25 So I think this is something that Congress

1 clearly had in mind, because you have to assume that
2 they knew about the regulation enacted by the agency
3 that was administering this statute, issued just months
4 before they enacted the counterclaim using the same --
5 the same --

6 JUSTICE GINSBURG: But what about the fact
7 that the FDA and not the patent holders were drafting
8 the use code at the time this legislation passed?

9 MR. HURST: Justice Ginsburg, that is
10 incorrect; your timing is incorrect. Prior to June of
11 2003 the FDA was authoring the use codes based on
12 information from the brand companies, but after
13 June 2003 the brand companies were authoring the use
14 codes and the statute was enacted after June of 2003.

15 JUSTICE KAGAN: So you are suggesting
16 that --

17 JUSTICE KENNEDY: When the FDA was writing
18 the codes, was it writing about the scope of the patent?
19 Or was it writing about labeling?

20 MR. HURST: It was writing about the scope
21 of the patent. The use codes have always been about the
22 scope of the method-of-use patent; it has never been
23 about anything other than the scope of the method-of-use
24 patents. The only --

25 JUSTICE KENNEDY: We can ask the government,

1 but why did it think that it lacked the expertise,
2 because it didn't want to opine under the patent laws?

3 MR. HURST: I think the short answer is yes;
4 the FDA has always done their very best to not get
5 anywhere near the patents. They don't do patents,
6 essentially, and so they decided -- and there was a --
7 there was a notice and rule -- I'm sorry, notice and
8 comment rulemaking about this, and eventually they
9 decided to make -- to have the brands submit the use
10 code.

11 JUSTICE KENNEDY: Would it suffice in the
12 description just to give a cross-reference to the
13 patent, to say the use of this drug as described in
14 patent claim number 43?

15 MR. HURST: It -- it would not be
16 sufficient, because the way -- the whole purpose of the
17 use code is to administer section (viii). So what the
18 FDA does is they take the use code, and they match it up
19 with the label, and then the generic gets to carve out
20 whatever the brand company says is patented via the use
21 code.

22 JUSTICE SOTOMAYOR: Counsel --

23 MR. HURST: But if I could get back to a
24 question, Justice Scalia, that you asked about the --
25 whether correcting typos in patent numbers is a real

1 role for the correction remedy. I would submit it is
2 not. And for all practical purposes, Novo is asking you
3 to eliminate the correction remedy from this statute,
4 and here's why. Think about what they are saying.

5 Novo is saying that the brand company
6 decides to put the patent in the Orange Book, but
7 somebody transposes two numbers. There is a -- there is
8 a mistake that's made. What does that mean in concrete
9 terms? Well, if you transpose the two numbers, the odds
10 are astronomically high that the brand company is citing
11 a patent that they don't own and that certainly doesn't
12 relate to the drug in question. It might relate to tire
13 treads; who knows?

14 But you do not -- Congress did not enact a
15 Federal cause of action to address typos in patents.
16 The brand company has every incentive in the world --
17 and the generic company has no incentive to file a
18 lawsuit to fix that. But the brand company has every
19 incentive in the world to ensure that they don't make
20 such mistakes, because there is a statutory benefit to
21 properly listing patents.

22 JUSTICE SOTOMAYOR: Counsel --

23 JUSTICE SCALIA: So it -- it's -- it's --
24 the issue is not whether Congress enacted it only for
25 that. The issue is whether Congress enacted it for that

1 in addition to a lot of other stuff.

2 MR. HURST: But --

3 JUSTICE SCALIA: I mean, it's a very small
4 detail, you know -- "correct." You are saying this one
5 word, "correct," in this immense bill with all sorts of
6 cause of actions and other provisions here and there;
7 that one word has this, this minimal meaning.

8 MR. HURST: You have --

9 JUSTICE SCALIA: It's conceivable.

10 MR. HURST: You have to give it some
11 meaning. You have to give it some practical meaning.
12 And right now -- and it's only -- the counterclaim has
13 only two remedies, so Novo is arguing that the first of
14 the two remedies is practically nonexistent.

15 JUSTICE SOTOMAYOR: Counsel --

16 MR. HURST: There is no role -- I'm sorry.

17 JUSTICE SOTOMAYOR: I'm sorry. Finish
18 answering.

19 MR. HURST: There is no role whatsoever. It
20 is surplusage by any definition to -- to say that --
21 "correct" is surplusage by any meaningful definition.
22 If you even put a dose of realism to this, "correct" has
23 no role under Novo's reading, while we preserve a
24 distinct role for both the correction and the deletion
25 remedy.

1 JUSTICE SOTOMAYOR: I will wait for your
2 rebuttal.

3 MR. HURST: Thank you. I'm sorry, Justice.
4 Sotomayor.

5 CHIEF JUSTICE ROBERTS: Thank you, counsel.
6 Mr. Horwich.

7 ORAL ARGUMENT OF BENJAMIN J. HORWICH

8 ON BEHALF OF THE UNITED STATES,

9 AS AMICUS CURIAE, SUPPORTING THE PETITIONERS

10 MR. HORWICH: Mr. Chief Justice, and may it
11 please the Court:

12 I would like to pick up with Justice
13 Kennedy's question about FDA and writing use codes. The
14 first thing I'd point out is that before 2003, although
15 FDA wrote the actual text that went in the Orange Book,
16 it was relying on information submitted on a sort of
17 free-form declaration by the -- by the brand. So the
18 brand was still kind of -- excuse me -- calling the
19 shots in that -- in that respect.

20 But the -- but the more important point is
21 that the FDA doesn't have the resources or expertise
22 or -- to engage in the substantive patent evaluations
23 that, that would be required under a theory where you
24 would go sue the FDA if you had a problem with this.
25 But more to the point --

1 JUSTICE GINSBURG: Mr. Horwich, do we -- do
2 we know what FDA's position is in this case? Is the
3 position you are presenting the position of the FDA?

4 MR. HORWICH: We -- yes. We represent the
5 United States here, and so we -- we speak -- we speak
6 for FDA and the other agencies of the government who are
7 very concerned here about the competition law effects of
8 this. I mean, that's -- that's in some ways the bigger
9 story here.

10 JUSTICE KAGAN: Well, Mr. Horwich, what does
11 that mean exactly, that you represent? I mean, this
12 might be a case where we would give the agency
13 deference, except the agency's name doesn't appear on
14 the brief. So should we give you any deference?

15 MR. HORWICH: Well, the names on the brief I
16 think should not be a guide to the deference question.
17 But we are not really claiming deference in the sense --
18 because what we are construing here, what the Court is
19 construing here, is the counterclaim provision, which is
20 a Federal cause of action. So the Adams Fruit decision
21 of this Court would say that agencies don't get
22 deference in defining the terms of a Federal cause of
23 action.

24 We do think that -- we do think that it's
25 important to recognize that Congress and the agency were

1 engaged in a dialogue in 2003. And although I wouldn't
2 label that deference, I would -- I would probably
3 characterize it more accurately as Congress building
4 upon what FDA had done in constructing its patent
5 information regulation and Congress saying, we need a
6 means to -- to protect the integrity of the system FDA
7 has set up.

8 JUSTICE KENNEDY: Just one more question on
9 how this works. Why does the FDA rely on use codes in
10 the Orange Book to make the carve-outs if it doesn't do
11 anything to ensure the accuracy of the code?

12 MR. HORWICH: Well, the statute -- well, let
13 me start with the basic that the statute envisions that
14 there will be carve -outs. That's the whole principle
15 behind section 8. And so FDA says, well, we need to
16 know when a generic has made a valid carve-out. And FDA
17 says, and FDA goes through this in the 2003
18 rulemaking -- if you read through the preamble there is
19 more detail. But the short of it is FDA has three
20 choices.

21 It could rely on the generics to say that
22 they've carved out, but that doesn't really work because
23 the generics could say something and then get on the
24 market when they hadn't proper carved out and that kind
25 of defeats the whole point of Hatch-Waxman's principle

1 of getting patent issues resolved before regulatory
2 approval.

3 FDA could, as a second alternative, try to
4 evaluate statutes itself. But nowhere else in the
5 statute is FDA given any role in the substantive
6 evaluation of patents, and with good reasons. This
7 Court has said in its Markman decision that claim
8 construction of patents is a question of law. The
9 actors in our system that decide what patents mean are
10 courts and ultimately this Court; it's not FDA.

11 So the third choice --

12 JUSTICE ALITO: If the patent holder -- if
13 the patent holder writes a use code that is
14 ridiculously, totally, unreasonably broad, is there
15 anything that FDA can do about that?

16 MR. HORWICH: Well, I think the problem,
17 Justice Alito, is that from FDA's point of view it's a
18 very slippery slope, because as soon as FDA starts
19 undertaking criticism of a use code its effective -- the
20 only basis for criticizing it is looking at the patent.
21 Now, this may be a very easy case, but the Court
22 shouldn't be fooled that all cases are going to be easy.
23 And if FDA here were to go in and said, well, this
24 doesn't look like it's the same as the claim of the
25 patents, in the next case, where it's a more difficult

1 question, where there may be some very good faith
2 dispute between the parties about the very meaning of
3 the patent, FDA is going to have to make a decision one
4 way or the other, and it's going to get sued.

5 JUSTICE ALITO: Well, what about after --
6 what about after there has been litigation and a court
7 has decided that a use code that was written in a
8 particular case was totally unreasonable? Does that
9 mean that the writing of that was in violation of some
10 provision of the Food and Drug Act or FDA regulations
11 and that there would be some sanction against the
12 company that did that?

13 MR. HORWICH: Well, I think the -- I think
14 the only posture in which a court would actually look at
15 a use code and evaluate it is under the counterclaim.
16 The court would not be looking at a use code under
17 traditional paragraph IV litigation, and so the author
18 of the majority opinion below was kind of mistaken in
19 that regard.

20 CHIEF JUSTICE ROBERTS: What about an APA
21 action against the FDA for relying on the use code?
22 Couldn't that be challenged as arbitrary and capricious?

23 MR. HORWICH: Well, it seems to me that that
24 challenge would fail because FDA has made a reasonable
25 construction of the statute, that its role its role is

1 ministerial, it does not engage in substantive
2 evaluation of patents because the statute doesn't
3 envision that. So FDA would win that suit.

4 On the other hand, if -- going back to my
5 answer to Justice Kennedy, if we are talking about kind
6 of a second scenario where FDA does engage in
7 substantive patent review, yes, FDA could get sued. But
8 the problem with that is that FDA is going to get sued
9 in an APA suit, the real parties in interest are going
10 to be the generic and the brand, FDA is not going to be
11 owed any deference because it's going to turn on a
12 matter of claim construction, which is a question of
13 law.

14 JUSTICE KENNEDY: So how do you describe
15 what the FDA does? What's your third?

16 MR. HORWICH: So what FDA does do is it
17 accepts the submission from the brand describing its --
18 describing its use code. And FDA says in its 2003
19 rulemaking: We are trying to do the best we can through
20 the administrative process to get good information in
21 the first instance.

22 JUSTICE KAGAN: And it's your understanding
23 that you require companies to state the scope of the
24 patent in the use code, or might you think it's
25 perfectly permissible for a company to write its use

1 code in terms of indications?

2 MR. HORWICH: It's certainly possible in a
3 particular case that the indications would be
4 appropriate. This is -- what we are asking for in the
5 use code is something that's good enough to do the job
6 that the use code is intended for, which is to inform
7 FDA --

8 JUSTICE SOTOMAYOR: But you said that --

9 MR. HORWICH: -- what needs to be carved
10 out.

11 JUSTICE SOTOMAYOR: Except, counsel --

12 JUSTICE KAGAN: So that -- I'm sorry, go
13 ahead.

14 CHIEF JUSTICE ROBERTS: Justice Sotomayor.

15 JUSTICE SOTOMAYOR: Except the FDA tells
16 parties not to rely on the orange code.

17 MR. HORWICH: It --

18 JUSTICE SOTOMAYOR: It tells them what
19 controls is the patent.

20 MR. HORWICH: Well, that is true that FDA
21 said that the parties should look at the patent. But
22 what FDA said in its 2003 rulemaking is that it would
23 rely on the use code.

24 Let me also point --

25 JUSTICE SOTOMAYOR: Could I ask you --

1 MR. HORWICH: I'm sorry.

2 JUSTICE SOTOMAYOR: -- just on a practical
3 basis. I understand that the Petitioner has filed an
4 amended label in 2010. I presume that that amended
5 label copies the current label with the exception of
6 substituting the manufacturer.

7 MR. HORWICH: The label -- I can't speak to
8 what the labeling in the application is right now,
9 because it's confidential.

10 JUSTICE SOTOMAYOR: But let's assume
11 that's --

12 MR. HORWICH: But if we assume for the sake
13 of argument that it's the same, yes.

14 JUSTICE SOTOMAYOR: Now, it claims that when
15 the paragraph IV -- the paragraph IV action is started
16 and it's sued for infringement, that it's automatically
17 going to lose --

18 MR. HORWICH: Well, that's right, and in
19 fact --

20 JUSTICE SOTOMAYOR: -- because --

21 MR. HORWICH: In fact, Caraco has stipulated
22 to that. That's at joint appendix 177, because it
23 includes the --

24 JUSTICE SOTOMAYOR: Could you explain to
25 me -- could you explain to me why? Is merely the use of

1 a label that's identical infringement or is it an
2 infringement of the underlying patent?

3 MR. HORWICH: It would be inducement of
4 infringement to sell a product with labeling that
5 suggests that the product be used for a patented method
6 of use.

7 JUSTICE SOTOMAYOR: Okay. So tell us how a
8 court gets out of the quandary of there being a claim
9 that is stipulated to -- I've infringed -- and then how
10 does it deal with the counterclaim? Now, the district
11 court just ignored the act of infringement below and
12 went straight to the counterclaim. But I'm not quite
13 sure how you get out of the quandary that this creates
14 for the courts and the parties.

15 MR. HORWICH: The counterclaim is designed
16 precisely to get out of the quandary, because what it
17 says is the paragraph IV litigation here, the choice
18 between infringement and noninfringement, is a false
19 choice, because if the counterclaim prevails and the use
20 code changes the paragraph IV litigation is going to go
21 away because Caraco is going to want to go proceed
22 through section (viii). It's going to be able to carve
23 out and get approval that way without a judgment in the
24 paragraph IV litigation.

25 JUSTICE SOTOMAYOR: Let's assume that Caraco

1 puts in a label like the one it wants to use under claim
2 4. Will the FDA just kick it out?

3 MR. HORWICH: Yes. It's not -- it's not
4 permissible.

5 JUSTICE SOTOMAYOR: It will not even ask for
6 a response from Novo?

7 MR. HORWICH: FDA will not permit -- does
8 not permit -- will not approve the application where
9 theirs is carve-out combined with section -- with
10 paragraph IV.

11 JUSTICE SOTOMAYOR: But is that before --
12 without an infringement action by Novo?

13 MR. HORWICH: I'm not sure of the timing.
14 Of course, it's possible. The paragraph IV litigation
15 is somewhat in the control of the parties, so it's not
16 as if FDA sends out the notices that could trigger the
17 litigation. But there might not be -- there might not
18 be --

19 JUSTICE SOTOMAYOR: If you tell me the FDA
20 doesn't want to get involved in construing the patent,
21 why is it kicking out the claim for, claim for, claim
22 until Novo does a suit on whether or not the generic is
23 infringing or not --

24 MR. HORWICH: I --

25 JUSTICE SOTOMAYOR: -- and let that issue be

1 decided below?

2 MR. HORWICH: From FDA's point of view, it's
3 not a sufficient application if there's carveout
4 labeling presented with a paragraph IV certification.
5 And I'd also say this. To take a step back, the fact
6 that there might be conceivably alternative remedies
7 under some other construction of the operation of the
8 statute shouldn't make you think the counterclaim isn't
9 available here. After all, the situation that Novo
10 agrees --

11 CHIEF JUSTICE ROBERTS: Finish your
12 statement.

13 MR. HORWICH: Thank you.

14 -- the situation Novo agrees is covered by
15 the counterclaim, where the patent doesn't belong in the
16 Orange Book at all, is one that can be remedied at some
17 expense and delay through paragraph IV litigation by
18 proving noninfringement if the patent's irrelevant.

19 CHIEF JUSTICE ROBERTS: Thank you, counsel.
20 Mr. Perry.

21 ORAL ARGUMENT OF MARK A. PERRY

22 ON BEHALF OF THE RESPONDENTS

23 MR. PERRY: Mr. Chief Justice and may it
24 please the Court:

25 I think the last half-hour has made clear

1 that what really is at issue here is a challenge to
2 FDA's administration of the Orange Book. That is an APA
3 challenge, not this counterclaim.

4 Justice Kennedy, you asked if when FDA was
5 writing the use codes did it describe the scope of the
6 patent, and Mr. Hurst said yes. That's false. The
7 answer is no. For example, if I could point to the
8 joint appendix at page 522, these are some FDA-authored
9 use codes. Everything before U530 is an FDA-authored
10 use code. U275.

11 CHIEF JUSTICE ROBERTS: I'm sorry. What
12 page have you got?

13 MR. PERRY: Page 522, Your Honor.

14 CHIEF JUSTICE ROBERTS: Thanks.

15 MR. PERRY: U275, "Method of use of the drug
16 substance." U278, "Method of use of the indication of
17 the drug product." U279, "Method of use of the approved
18 product." These were the ones that the FDA wrote when
19 it was responsible for writing use codes to put the
20 world on notice.

21 So U-278, method of use of the indication of
22 the product, the patent relates to secondary
23 hyperparathyroidism, but you will never know that from
24 the use codes, and that's when the FDA was writing it.

25 In 2003, FDA decided to turn it over to the

1 industry. And it said in this rule making, and you've
2 heard about the rule making but not what FDA actually
3 said. It said to this: "We believe," and I am quoting
4 by the way from page 19 A of the reply brief. This is
5 68 Federal register page 36,682. "We believe an
6 approach that requires the NDA applicant or holder or
7 patent owner to identify the approved methods of use
8 protected by the patent is most consistent with the
9 general balance adopted in the Hatch-Waxman Act. And
10 then the generic industry during this very rule making
11 made all of the arguments that Mr. Hurst has made today,
12 said we should have more of a challenge, we should have
13 litigation and so forth, and the FDA said no, that's not
14 right, because that would let the generics pick it.

15 And we said -- they said, we shouldn't do
16 that. And this is important. This is on page 24(a) of
17 the reply brief. The FDA said very clearly, "There
18 would be repeated litigation over individual patent
19 lifting decisions." That's a bad idea, the FDA said,
20 because there is no assurance that NDAs would be
21 approved sooner or generic drugs would enter the market
22 any more rapidly.

23 CHIEF JUSTICE ROBERTS: But the alternative
24 is that the FDA is going to have to hire an awful lot of
25 patent lawyers to review the use codes and their

1 correspondence to the actual patents.

2 MR. PERRY: There are several alternatives,
3 Your Honor. First, the FDA could de-link the
4 indications from use codes. Right now the regulations
5 say that you can base your use code on the indication or
6 use code as identical or indication applies with every
7 regulation.

8 You didn't hear Mr. Horwich say that FDA
9 thinks our use code is wrong. FDA has accepted our use
10 code. Caraco filed an administrative challenge to the
11 use code arguing that it was arbitrary and capricious
12 under the APA. And that's the way agency actually gets
13 challenged in the ordinary course as this Court has seen
14 it many times. Not here.

15 CHIEF JUSTICE ROBERTS: Well, that's the way
16 agency action gets challenged when it's substantive
17 action. The FDA's position, the United States position
18 is that this is purely ministerial act.

19 MR. PERRY: Your Honor, they have chosen to
20 make it a ministerial act, which is not a negative, by
21 the way. It is the Federal Drug -- Federal Food and
22 Drug Administration. What they do is administer this
23 program. And they have in other areas, such a patent
24 term extensions, entered into memorandums of
25 understanding with PTO where there are patent issues so

1 that there is interagency cooperation to deal with
2 patent issues. They could do that here but they have
3 chosen not to, and in the exercise of their enforcement
4 discretion said: We are going to accept the ANDA
5 applicant's submission.

6 And, more importantly, FDA has made the
7 policy decision to tie the section viii determination to
8 the use code. They don't have to do that. That's not
9 in the statute. They could change that by rule making.
10 And third, on the indication, for example, Novo's use
11 code always follows the indication. The change in this
12 case is because FDA changed the indication.

13 JUSTICE SOTOMAYOR: What odds would you
14 put --

15 MR. PERRY: I'm sorry?

16 JUSTICE SOTOMAYOR: What odds would you put
17 as a betting lawyer on them winning a challenge to the
18 FDA policy decisions of what its capable of doing and
19 not doing?

20 MR. PERRY: Your Honor, there have been
21 about a dozen APA challenges to various aspects of this
22 administration in the DC Circuit over the past ten
23 years. The generics have won several of them including
24 most importantly the Purepac case that we cite in our
25 brief which is direct challenge to FDA's refusal of a

1 section viii carveout because of the use code, and the
2 generic won that argument. It said it was arbitrary and
3 capricious for the agency to do what it did. So --
4 look, every APA battle is an uphill battle. They're the
5 plaintiff. They burden -- the burden of proof. It is
6 an available remedy. You couple that, Your Honors,
7 with the--

8 JUSTICE GINSBURG: What you described
9 sounded very much like this case. So if the -- what was
10 the D.C. Circuit case? If -- if the DC Circuit said its
11 arbitrary and capricious not to -- to just accept the
12 brand's use code --

13 MR. PERRY: In Purepac, Your Honor, the
14 brand changed its position but the FDA did not change
15 its position accordingly. And that was the
16 arbitrariness there. Here of the brand changed its
17 position and the FDA went along. So I don't think they
18 would win that case, to be clear, in our particular
19 facts. That's because Novo has done nothing wrong. I
20 mean, you've heard about, a lot about over breadth,
21 misleading, blah, blah, blah. There is nothing wrong
22 with Novo's use code if the agency agrees with that.

23 JUSTICE BREYER: Can I bring you back for a
24 minute, please, to the statute, and if you -- it's in
25 page 3 of the blue brief. And in just reading it, I

1 might be missing something which you will point out to
2 me, I'm sure. But if you get the statute at the bottom
3 of the page, it says, as I --if you've got it there,
4 right?

5 MR. PERRY: Yes, Your Honor.

6 JUSTICE BREYER: It says, "If the ANDA
7 Holder," now that's -- that's Novo, "holder of the
8 approval-- the approval Holder for the drug, a" -- I'm
9 skipping words -- "a use of which is claimed by the
10 patent" and that's what you are doing -- what's that use
11 was, and I look at page 12 and the use is "a method for
12 improving glycemic in adults with type 2 diabetes
13 mellites."

14 So that's the use that you're -- that's the
15 use that's claimed by the patent. "If you bring a
16 patent infringement action against the ANDA applicant,"
17 that's them, "the ANDA applicant may assert a
18 counterclaim, which they want to do, seeking an order
19 requiring the holder to correct the patent information
20 on the ground that the patent does not claim an approved
21 method of using the drug."

22 So I look at that with those words -- I've
23 skipped words. I look at those words and I say that's
24 what they are saying. They are saying the use that --
25 that it -- that your patent does not cover a portion of

1 the set of things described by your use. And therefore
2 they would like to correct the description so that the
3 description no longer covers something that you do not
4 have -- a use that you do not have a patent on. Now
5 that would seem to me to fit within those literal words.
6 And of course the purpose is what we have been arguing
7 about. But just looking at the literal words, why
8 doesn't it fit?

9 MR. PERRY: Justice Breyer, your question
10 conflated as Caraco often does, the use and the
11 indication. You quoted the indication, that is, a
12 method of improving hypoglycemic control. The use is
13 repaglinide combined with metformin. They are disclosed
14 in different parts of the label. The indication is
15 under indications, and the use is under dosage and
16 administration. That is the way FDA has always
17 administered this, and that's the distinction between
18 indication and method of use, which why the regulations
19 and the form are written in the alternative.

20 JUSTICE BREYER: In other words, you are
21 saying that the -- this -- a method for improving
22 glycemic control in adults with type II diabetes
23 mellites is not the patent information.

24 MR. PERRY: Your Honor, that is the
25 indication that --

1 JUSTICE BREYER: I know, but are saying it
2 is patent information?

3 MR. PERRY: It is not patent information
4 submitted under (b) or (c) of section 505 which is the
5 statutory language. It is information submitted under
6 314.53(p) and (e) of the regulation, which is a different
7 question.

8 JUSTICE KAGAN: Was not the regulation
9 issued under this statutory section?

10 MR. PERRY: No, Your Honor. The regulation
11 was issued under section 701, the general rulemaking
12 authority. They cite section 505, but there was a
13 subsequent rulemaking when Pharma, the trade association
14 for the branded industry, challenged FDA's authority to
15 require all this information. And then in 2007
16 rulemaking that my friends on this side never cite, FDA
17 came back and explained that our -- that the patent
18 submission reg is based on section 701 to facilitate the
19 section viii and ANDA process, not an interpretation of
20 section 505. And there are lots and lots of
21 interpretations of the statute. Drug --

22 JUSTICE SCALIA: Can you give us of a cite
23 of that, please?

24 MR. PERRY: I'm sorry, the 2007 rulemaking
25 is --

1 JUSTICE SCALIA: You don't have to do it
2 now. Just file it with the Court. I don't want to eat
3 your time up.

4 MR. PERRY: You Honor, it is cited in our
5 brief and my colleague will hand up to you momentarily.

6 JUSTICE SCALIA: Oh, it's cited in principal
7 brief?

8 MR. PERRY: In the red brief, Your Honor.

9 JUSTICE SCALIA: Yeah. Don't waste your
10 time. Go ahead.

11 MR. PERRY: Justice Breyer --

12 JUSTICE SCALIA: I don't really care.

13 MR. PERRY: To further answer your
14 question--

15 JUSTICE BREYER: I do. Maybe your colleague
16 can find it for you.

17 MR. PERRY: Justice Breyer, there is another
18 point on the structure of the statute. If you look at
19 the chart in the back of our red brief where we tried to
20 lay out the various provisions of the actual statute,
21 the counterclaim that the Court read and that we are
22 focused on talks about "a" use. And in the preamble it
23 says, "If the patentholder claims a use --

24 JUSTICE BREYER: You know, I know that
25 argument, right?

1 MR. PERRY: So --

2 JUSTICE BREYER: You don't need that
3 argument. If you're right that the patent information
4 in this particular provision does not have anything to
5 do with or at least does not cover the words about
6 diabetes I just read, well, then I guess this section
7 would have nothing to do with it because those are the
8 words they want corrected, aren't they?

9 MR. PERRY: That's correct, Your Honor.
10 There's a section --

11 JUSTICE KAGAN: Mr. Perry, in your view,
12 patent information is just the patent number and the
13 expiration date, and that's all?

14 MR. PERRY: The patent information submitted
15 under (b) and (c) of section 505, correct, Your Honor.

16 JUSTICE KAGAN: Is that just the patent
17 number and the expiration date?

18 MR. PERRY: That's right. And we know that
19 because the Congress at the same time debated it, an
20 alternative bill that was sponsored by the Democrats
21 that had lots and lots of additional patent information.

22 JUSTICE KAGAN: Well, why would anybody have
23 created this counterclaim to fix the patent number and
24 the expiration date when that can be done by way of the
25 defense to a patent claim?

1 MR. PERRY: Your Honor, it's important to
2 remember the counterclaim is only a delisting provision.
3 It is a very narrow provision. The FTC report that's
4 cited in the briefs identified eight cases in the first
5 18 years of Hatch-Waxman that raised this problem of
6 improper listing, mostly due to successive 30-month
7 stays. That was fixed in the counterclaim, and the
8 30-month stays were fixed and there has never been a
9 case since -- since 2003 there has never been --

10 JUSTICE GINSBURG: What was fixed? I missed
11 what you said. What was fixed in the counterclaim?

12 MR. PERRY: The counterclaim addressed the
13 problem of improper listing that was addressed in the
14 FTC report. The purpose of the counterclaim, according
15 to its sponsors, and according to the conference report,
16 the listing of improper patents, that problem has gone
17 away. There is no such problem any more. It has never
18 come up again. The counterclaim was entirely successful
19 in solving the problem that Congress set out to address.
20 It had nothing to do with use codes.

21 JUSTICE SCALIA: What do you mean by the
22 problem of improper listing?

23 MR. PERRY: Your Honor, what the FTC report
24 explained was that certain branded companies near the
25 expiration of the listed patent would come in and file a

1 second patent in the Orange Book, even though it was not
2 properly listed, it didn't fit within section 505(b) in
3 the listing requirements, solely for the purpose of
4 getting a second 30-month stay, essentially to box out
5 the generic companies; And that that was an
6 anticompetitive action.

7 They recommended the counterclaim to fix
8 that, and at the same time the FTC said if Congress were
9 to enact such a counterclaim it is unclear how
10 frequently it ever would be used. So this was always
11 intended to be a very narrow -- it's not a fix-all
12 remedy.

13 JUSTICE KAGAN: So your argument, Mr. Perry,
14 is not just that the word "correct" does no work. Your
15 argument is that the entire provision no long does any
16 work?

17 MR. PERRY: No, Your Honor. My argument is
18 very simple. A delisting question, it's an on/off
19 switch. Either the patent is properly listed in the
20 Orange Book or it's not. The counterclaim gives the
21 generic a one-shot knock-out remedy. If it's not
22 properly delisted it goes away, and a bunch of things
23 follow from that. There is no 30-month stay, there is
24 no paragraph IV litigation, there is no impediment to
25 FDA approving the ANDA, because if the patent isn't

1 listed in the Orange Book then a whole separate set of
2 ANDA approval requirements kick in. A use code is
3 nothing like that.

4 CHIEF JUSTICE ROBERTS: I'm still not
5 following it. It's not listed simply because the number
6 is wrong?

7 MR. PERRY: Your Honor, the usual case is
8 it's not listed because it doesn't fit. The most famous
9 example, the Buspar case that claimed a metabolite
10 rather than the drug substance and that wasn't the
11 proper listing for that reason.

12 The correction language which does come out
13 of the other bill, the alternative bill, and we do think
14 is an artifact as the language is used, is there to give
15 flexibility to courts. If you have a situation of an
16 improperly listed patent, then the court has more
17 flexibility than simply delisting.

18 CHIEF JUSTICE ROBERTS: The brand
19 manufacturer has an overwhelming incentive to list the
20 correct patent, doesn't it?

21 MR. PERRY: Yes, Your Honor.

22 CHIEF JUSTICE ROBERTS: So why would we give
23 a procedure to an adversary to fix the number when the
24 brand manufacturer is going to fix it as soon as its
25 alerted to the problem?

1 MR. PERRY: Because, Your Honor, if the
2 generic raises a counterclaim and if it's delisted, the
3 generic gets no more 180-day marketing exclusivity stay
4 at the end of the ANDA process. If it's corrected
5 through a different patent number, the generic would
6 still have its 180-day exclusivity.

7 So there is every incentive for the generic
8 to bring a counterclaim for a correction if that's the
9 appropriate remedy. And again, it just gives more
10 flexibility to the courts. That is something that very
11 much would benefit the generic and it would be available
12 use of the word "correct." It may be an unusual one,
13 but it's certainly available.

14 JUSTICE GINSBURG: I can't imagine that that
15 would really come to -- I mean, if it's a transposition
16 of numbers, that there would have to be a proceeding to
17 get it changed. I mean, the minute that was noticed, I
18 assume that the brand manufacturer would change it.

19 MR. PERRY: Your Honor, the transposition is
20 not the problem. The more frequent -- the way we think
21 it would come up is these branded companies have large
22 portfolios of patents, they list many patents in the
23 Orange Book. You know, Novo has five or six right now.
24 Other companies have many more, dozens and dozens. They
25 write these use codes and they associate them with the

1 patents. And in the Orange Book -- by the way, it is
2 called "the Orange Book" because it's orange. And it's
3 thick. It's got a lot of information in it. It has to
4 list every single approved drug with the use code. I
5 mean, it's just pages and pages of numbers is what's in
6 here.

7 It's not a transposition of numbers, but
8 rather the listing of one patent and improperly
9 associating it with a drug. That could be corrected
10 through this counterclaim. But again, that's worlds
11 away from this use code challenge, which is really what
12 Caraco wants to bring, something that wasn't on
13 Congress's radar screen because FDA wrote the use codes
14 at that point.

15 JUSTICE SOTOMAYOR: Counsel, let's assume,
16 because I now take from your earlier conversation with
17 Justice Breyer that you're saying the use code here is
18 absolutely right, because the only use that we claimed
19 was the combination use of the drug, your drug with the
20 metformin. But the only thing that is wrong here is the
21 indication that the FDA has required. So that's not
22 even wrong because you have no choice about that; is
23 that correct.

24 MR. PERRY: That -- the indication is
25 correct.

1 JUSTICE SOTOMAYOR: What this means
2 practically I believe is that when your patent expires
3 no generic can come in with a use that's different than
4 yours because they're going to be boxed out by this
5 indication, this overbroad indication. Do you actually
6 think that that's what Congress intended? I thought
7 with claim 4 and section viii that what Congress
8 intended was to ensure that drugs got onto the market as
9 quickly as possible.

10 MR. PERRY: Your Honor, that argument was
11 made to the FDA by the generic industry in the 1994
12 rulemaking, the first time this issue came up, and they
13 said: You should not allow use codes to be based on
14 indications; you should instead require a description of
15 the patented method-of-use. You heard Mr. Hurst say
16 that again this morning. Here's what FDA said in
17 response. It's page 59, Federal Register page 50,346,
18 quote: "For a use patent, FDA includes in the Orange
19 Book a code identifying the indication covered by the
20 patent. We decline to expand the Orange Book to include
21 patent descriptions." Then it went on to explain that
22 persons interested in patent descriptions should consult
23 the official gazette --

24 JUSTICE BREYER: Yeah, but what it also says
25 is this, and that's what I want to go back to this

1 literal statutory argument. We took the words, because
2 this is what you can correct. What you can correct, the
3 statute says, is you can correct "patent information
4 submitted by the Holder under subsection (B) or (C)."
5 So we look at (B), and what (B) says is (B) tells us
6 that you are supposed to submit in respect to where you
7 claim the use of a drug the patent number and the
8 expiration date.

9 So, so far that seems to support you. But
10 then we look at the regulations which the FDA
11 promulgated, I take it promulgated in respect to (B) and
12 (C), particularly the sentence I read, or maybe some
13 similar sentence, and it tells you that you have to
14 provide the description of the patented method of use as
15 required for publication. So now I go back and look at
16 what you did provide. And what you did provide was you
17 provided -- you said that what we do, we have a method
18 for improving glycemic control in adults with type II
19 diabetes mellitus.

20 That seems to fit directly under (iii) of
21 the FDA's requirement and that FDA requirement was an
22 expansion of (B)and therefore it sounds to me as if
23 when they say "correct," "correct the patent
24 information," it includes the sentence that you put
25 there that they would like to see corrected. Now,

1 what's wrong with that?

2 MR. PERRY: First, the regulation is not an
3 interpretation of 505(b). It's an implementation of
4 701. Second and more substantively, however, the
5 form -- you quoted accurately from Box 4.2(b) of the
6 form. There is also Box 4.2(a) of the form, which
7 includes the description of the method of use tied to
8 the label, which is required by subsection (P) of the
9 regulation that you were just quoting to me. In that
10 part of the form, Novo very carefully describes claim 4
11 of the patent and ties it to the dosage and
12 administration and clinical pharmacology sections of the
13 patent and calls out by reference combination trials.
14 The only combination trial in the label is the
15 metformin- repaglinide combination.

16 And in FDA -- that that is a sufficiently --
17 because these forms, by the way, you have got them in
18 here, are these little tiny boxes, you can't put very
19 much information in there. That is described in there.
20 It is not that every piece of information required by
21 the regulation -- the regulation has 19 lettered
22 questions, of which several have subparts, so it's 26
23 separate pieces of information. They are not all
24 provided in one box, Box 4.2(b). There is actually a
25 whole form. It's four pages long. We filled it all

1 out.

2 And there is an important point, Justice
3 Breyer. This is a summary judgment case. We put in a
4 declaration from an FDA expert -- it's in the record
5 before the Court -- explaining how every single box ties
6 to every single thing in the regulation. That's
7 absolutely undisputed on this record. There is no
8 contrary evidence as to Novo doing anything wrong. So
9 whether Congress -- to go back to this counterclaim, we
10 know Congress didn't intend it to reach this form,
11 because this form didn't exist when Congress was
12 debating the counterclaim.

13 JUSTICE BREYER: Now, the government -- now,
14 the government, which is representing all the government
15 agencies, whether the FDA signs it or not, tells us that
16 that language, that (b) and (c) language about patent
17 information as interpreted by the regs does cover this
18 stuff. This is about the most technical statute I ever
19 read --

20 MR. PERRY: Your Honor --

21 JUSTICE BREYER: -- and -- when I'm talking
22 about patent information among (b) and (c), we have the
23 government telling us that that covers this, and why
24 don't I just stop right there and say thank goodness I
25 am out of this case -- and I'm not out of it --

1 MR. PERRY: I think -- I think I can do no
2 better than refer the Court again to the 2007
3 rulemaking -- Justice Scalia, 72 Federal Register page
4 21268 -- which the United States does not address and
5 which Caraco does not address, in which FDA addressed
6 your point, Justice Breyer, and explained that this
7 information -- while useful, and we have never
8 challenged FDA's authority to require the information,
9 but it is not an interpretation of that language patent
10 information -- this quote (c) is --

11 JUSTICE SCALIA: And even if it were, as I
12 believe the government acknowledged, this is not a
13 situation in which we owe deference to the FDA. The
14 issue is whether a lawsuit can be brought or not.

15 MR. PERRY: Correct.

16 JUSTICE SCALIA: And we -- we don't decide
17 whether we have authority to decide cases on the basis
18 of what the agency thinks.

19 MR. PERRY: It is certainly --

20 JUSTICE SOTOMAYOR: What is the parade of
21 horrors that you imagine if we were to read the
22 counterclaim provision in the way your adversary is
23 promoting and the government is promoting? What --
24 what, presumably in the normal case and the one that the
25 regulations appear to expect is that the use code, the

1 indication code, everything is going to match the
2 patent. So in that situation, the counterclaim would
3 have no work to do.

4 So what is the parade of horrors?

5 MR. PERRY: Your Honor, first, the
6 counterclaim has no work to do for use codes. There is
7 a complete disconnect there, so --

8 JUSTICE SOTOMAYOR: I -- I'm asking you to
9 accept that we are to -- as an assumption only, don't --
10 it's not intended to be a -- a ruling -- to assume that
11 we read the counterclaim in the way your adversaries
12 want us to. What's the parade of horrors?

13 MR. PERRY: Your Honor, it is going to add
14 complexity, expense and so forth. The reason -- the
15 problems with all civil litigation, all new causes of
16 action -- and this was raised during the congressional
17 debates, when they proposed a freestanding cause of
18 action for generics to sue over a whole bunch of things,
19 Congress was up in arms, and said no, we are not going
20 to do that because we don't want to let private parties
21 into the FDA process.

22 This Court is familiar with that and the
23 parade of horrors from the Buckman case.

24 JUSTICE KAGAN: But, Mr. Perry, there are
25 also horrors on the other side, of course. I mean,

1 here's -- there's -- there's the statute, and it has
2 three provisions, and two of them are vague and one of
3 them works against you. One is an approved method. I
4 think, you know, you both go back and forth about it; it
5 depends on context. One is patent information, which,
6 you know, maybe you are right, and maybe Mr. Hurst is
7 right. It's not really quite clear what it means to be
8 under subsection (b) or (c). The third is correct. You
9 basically read "correct" out of the statute. So at
10 best, this is an unclear statute from your point of
11 view.

12 And then there is the question of what it
13 allows you to do.

14 The statute read your way essentially allows
15 you to unilaterally expand your patent in areas in which
16 it's quite clear that your patent ought not to go --
17 does not go -- but allows you to do that. So why should
18 we read the statute so that it effects a purpose that is
19 entirely antagonistic to the purpose that Congress had
20 in passing this statute, given that the statute is at
21 best from your perspective ambiguous?

22 MR. PERRY: Justice Kagan, this statute was
23 a political compromise. There is no debate on the
24 historical record about that.

25 And the compromise that Mr. Hurst indicated

1 earlier was that the statute would deal with some
2 things -- the counterclaim would deal with some things,
3 delisting -- and almost everything else would be turned
4 over to the FDA. And FDA had this extensive rulemaking,
5 that as Mr. Hurst said, Congress was aware of.

6 And during that rulemaking, Congress did
7 several things. First, it confirmed that the industry
8 would use the use code. Second, that use codes could be
9 based on indication. So there is no extension of the
10 patent monopoly. It is simply following FDA's
11 instructions as to indication of use code --

12 JUSTICE GINSBURG: Mr. Perry, can I ask you,
13 on that core question: we have a patent on a drug
14 alone. It expires, and then the patent holder gets a
15 label patent that's on a method of use, and we have a
16 generic that wants to sell the drug alone which is no
17 longer patented. Doesn't want to sell it in combination
18 with anything else. Wants to sell the drug alone.

19 Can it do so without infringing the method
20 of use patent?

21 MR. PERRY: No. Your Honor, we will -- they
22 will be sued for infringement if they ever go to market,
23 because the generic substitution laws present in 49
24 state require or allow pharmacists to substitute the
25 products whether or not the combination is on the label.

1 So there will always be an infringement suit, which gets
2 back to Justice Kagan's question: why would Congress
3 have contemplated? They didn't contemplate this. They
4 contemplated delisting, where you take it out of the
5 infringement suit altogether.

6 This issue, indications use code,
7 section viii, that is all within the agency, but there
8 is a litigation problem with it or challenge to it, that
9 is what the APA is for. And again, there have been
10 dozens of APA cases where the generics largely have
11 challenged FDA's determinations in that respect.

12 It is not what the counterclaim is for.
13 This is a very narrow provision. What we're -- we're
14 parsing, by the way, two clauses in one sentence of a
15 statute -- the 2003 amendments were 415 pages long. The
16 Hatch-Waxman Act is thousands of provisions long. Very
17 delicate balance between lots of competing interests,
18 billions of dollars at stake. And we have to be
19 careful. When Congress creates a new course of action,
20 the law of unintended consequences kicks in here.

21 We know this is not -- this case is not what
22 Congress intended. The counterclaim we don't believe
23 can be read it all to it. Even if it's ambiguous.
24 Putting it in context and looking at what FDA has
25 actually said about these matters in its rulemaking,

1 when it's faced with the same challenges that a generic
2 industry that Mr. Hurst presented here -- it has
3 rejected them over and over again --

4 JUSTICE ALITO: Come back to Justice Kagan's
5 question. Your position is really nothing can be done
6 by a generic that is blocked from marketing a drug for a
7 nonpatented use by a use code that -- that is -- that
8 seems to cover that use --

9 MR. PERRY: In this case, Justice Alito,
10 there were two points: first, FDA rejected Caraco's
11 administrative challenge to the use code. They could
12 have taken that to the D.C. Circuit under the APA.
13 Second, they have indicated a rejection of their section
14 viii carve-out because of the use code. They could take
15 that to the D.C. Circuit under the APA. That is the
16 usual course for challenging agency action.

17 If there are any problems here -- our
18 position is, we have complied in every respect at every
19 moment with every bit of FDA's regulations. And again,
20 that -- that's what the evidence in this record shows.

21 So again, I need to push back a little on
22 extensions and monopolies and so forth, because that's
23 not what this case is about. This case is about a
24 properly working administrative process, and should in
25 private litigation between two parties in which the FDA

1 will not be a party, should that regulatory regime be
2 dismantled. You know -- and we actually asked to bring
3 the FDA in, in this case. Novo did. And Caraco
4 resisted that.

5 You know, we think that if you're going to
6 debate the administration of the Orange Book, it should
7 be under the APA --

8 JUSTICE KAGAN: But -- but here's what we
9 know about Congress's intent. And it goes back to the
10 Mylan suit. What we know about Congress's intent is
11 that Congress wanted to give a generic manufacturer in
12 this situation a remedy when there was a completely
13 irrelevant patent. And the question is why we should
14 consider this to be any different. In some respects,
15 this makes -- this is worse from the generic
16 manufacturer's point of view because the generic
17 manufacturer doesn't even have a defense in an
18 infringement suit --

19 MR. PERRY: Your Honor --

20 JUSTICE KAGAN: -- so why should we think
21 that the Congress that really cared about the result in
22 Mylan does not care about this?

23 MR. PERRY: Mylan, in the response gives the
24 generic a one-shot remedy, and you are out of it
25 altogether. And it's a black-and-white decision. It's

1 an on-off switch. Either the patent is properly listed
2 or not. In a use code of the Orange Book, there are
3 over 1000 of them. They are shades of gray. There
4 are -- there are very specific ones, very general ones.
5 I read to the Court some of the ones that the FDA itself
6 wrote.

7 You would get into these long involved
8 questions about compliance and so forth -- to the
9 effect, Congress wanted to make generic approvals
10 quicker in the Mylan situation. FDA itself, and I
11 started out my argument reading from that page, page 24A
12 of the reply brief, where the FDA said increased
13 litigation over use codes -- patent listings -- would
14 not assure faster generic entry because you would spend
15 years and years, as we all have, litigating these very
16 issues.

17 So the Congress had it focused on this,
18 which it never did. There is not one word in the
19 thousands and thousands of legislation -- pages of
20 legislative history about use codes. Had it focused on
21 this, it would never have gone this way because it
22 didn't need to.

23 And when it did have the broader bill, SA12,
24 it failed.

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

1 Mr. Hurst, you have four minutes.

2 REBUTTAL ARGUMENT BY JAMES F. HURST

3 ON BEHALF OF THE PETITIONERS

4 MR. HURST: Thank you.

5 I would like to start by -- by asking the
6 Court if I can to turn to the Joint Appendix, second
7 volume, 484. And I want to address two issues: the
8 argument that the use code is disconnected from the
9 patent itself, and it -- it may relate to the indication
10 regardless of what the patent says; and whether or not
11 the information is being submitted under subsection (b)
12 and (c).

13 If you are at 484, this form went through
14 notice and comment rulemaking before the enactment of
15 the counterclaim. The title, "patent information
16 submitted," that -- this carries out the regulation
17 314.53, entitled "submission of patent information."

18 Now look at right below those two boxes.
19 What does it say -- how does it say the information is
20 being submitted? This is a form Novo signed. "The
21 following is provided in accordance with section 505(b).
22 That's 355(b) and (c) of the Federal Food and Drug and
23 Cosmetic Act.

24 Moreover, when the FDA issued this patent
25 submission regulation in its final rule, it cited 505 as

1 its legal authority. That's at 28J of the Blue Book.
2 It cited -- and it specifically called out subsections
3 (b) and (c).

4 So this is a regulation that was enacted
5 prior to the enactment of the counterclaim. And now --

6 JUSTICE SCALIA: And what do you say about
7 the -- the section cited by -- by your colleague?

8 MR. HURST: We address -- he's citing
9 something the FDA said in 2007. And if you actually
10 read it, we cited it -- we addressed this in our brief.
11 It actually says our -- our legal authority for doing
12 this was explained fully in 2003. And in 2003, the FDA
13 cites 505.

14 Can I turn you quickly to 487 now. This
15 addresses quite specifically this notion that the
16 indication can be used even if it's disconnected from
17 the patent. 4.2(b). Remember what the regulation says,
18 and Justice Breyer read this before. It's at 127A of
19 the appendix. But the regulation says that the brand is
20 required to "the description of the patented method of
21 use as required for publication."

22 They are supposed to provide that
23 information. And look what the actual instruction says.
24 It could not be more clear. 4.2(b), bottom right side.
25 "The answer to this question" -- this is where the brand

1 supplies the use code -- "the answer to this question
2 will be what FDA uses to create a use code for Orange
3 Book publication. The use code designates a method of
4 use patent that claims the approved indication for use."
5 It depends on what the patent claims "of a drug
6 product."

7 Then it goes on to explain why you need to
8 do that. Each approved use claimed by the patent should
9 be separately identified in this section and contain
10 "adequate information" -- this refers to section viii --
11 "adequate information to assist 505(b)(2) and ANDA
12 applicants" -- that's us -- "in determining whether a
13 listed method of use patent claims a use for which the
14 ANDA applicant is not seeking" -- that is precisely the
15 situation we were facing.

16 We have offered a construction of this
17 statute that is fully consistent with its text, its
18 structure and its purpose. And it really is the only
19 reading of the statute that carries out congressional
20 intent in terms of trying to prevent situations where
21 incorrect patent information is unfairly delaying
22 generic competition.

23 Up to this point right now, Novo has still
24 failed to identify any reason why anybody in Congress
25 would want the system to work as Novo posits, where the

1 brand company gets to supply an overbroad use code?
2 Without judicial review, without agency review? That
3 blocks admittedly noninfringing products from the
4 marketplace. And I -- and I submit that given the
5 addition of the correction remedy that would not be in
6 there if this was not designed to address use codes,
7 because that's the only thing that can be corrected
8 without remedy.

9 JUSTICE SOTOMAYOR: Going back to the
10 question that I had. And a more practical question --

11 MR. HURST: Sure.

12 JUSTICE SOTOMAYOR: As I read the record, in
13 April of '08, the FDA rejected your section viii
14 application.

15 MR. HURST: Yes.

16 JUSTICE SOTOMAYOR: All right? And it asked
17 you to submit an amended code. Your brief says we did
18 it in September. Is it anywhere in the record?

19 MR. HURST: The question is did we --

20 JUSTICE SOTOMAYOR: Did you -- you submitted
21 what the FDA requested for your claim 4, the amended
22 label?

23 MR. HURST: Yes, we did. And it's in JA777,
24 paragraph 20. It's a stipulated --

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

1 MR. HURST: Thank you, Your Honor.

2 CHIEF JUSTICE ROBERTS: The case is
3 submitted.

4 (Whereupon, at 11:06 a.m., the case in the
5 above-entitled matter was submitted.)

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